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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,773	12/30/2003	Sandra J. Regnell	015916-299	1067

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EXAMINER
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NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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11/28/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/749,773

Applicant(s)

REGNELL ET AL.

Examiner

Tuan V. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 21-26, 28-46, 51, 54-57 and 61-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20, 27, 47-50, 52, 53 and 58-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/30/03, 5/17/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Restriction Requirement***

1. According to the Response to Restriction Requirement filed on August 27, 2007, applicants elect Species 1 of Figures 14-17. Applicants assert that claims readable on Species 1 are claims 1-20, 27, 47-50, 52-53 and 58-60.
2. Examiner would like to thank applicants for pointing out that the apparatus claims are 1-60 and 68-74, not claims 1-50 and 68-74.
3. Applicant's election of the invention of Group I in the reply filed on April 14, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Now, claims 1-20, 27, 47-50, 52-53 and 58-60 are presented for examination. Claims 21-26, 28-46, 51, 54-57, and 61-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. **Claims 1, 2, 4-7, 9, 10, 12-20, 27, 47-49, 53 and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Fonger et al (U.S. 5,190,528).**
7. Referring to claims **1, 2, 4-7, 9, 10, 12, 20, 27, 47-49, and 53**, Fonger discloses (see Figs. 4(a)-5(c)) a transeptal left atrial cannulation system comprising: a polyurethane catheter 5 or dilator 5 having a tapered tip and a rounded distal end opening 13, further, the distal portion of catheter 5 or dilator is curved (see Fig. 5(a)-5(c)) and the catheter 5 defines a first transverse cross-sectional area proximal to the distal end opening 13 and the distal end opening of the catheter 5 defines a second cross-sectional area less than the first cross-sectional area; a stainless steel tube 15 or sleeve, which abut with the shoulder of the catheter 5 or dilator (see Fig. 5(b) and col. 4, lines 62-68), movable within the hollow distal portion of the catheter 5 or dilator; and a stainless steel needle 9; and sheaths 3, 31 (see col. 5, lines 38-55).
8. Referring to **claims 13-19**, Fonger also discloses (see Figs. 5(b)-5(c)) a single metal tube with a narrowed distal end such that a predetermined length of tube projected out of the catheter orifice 13 but a thicker tube width is stopped at the orifice may be substituted for tube 11 and 15 wherein 11 and 15 fixed to a molded PETG copolyester hub 29 (see col. 4, line 65 to col. 5, lines 5), thusly, Fonger discloses the sleeve comprises the following: at least two portions, at least a metal distal portion, the metal distal portion extends around a portion of the needle 9 (see Fig. 5(c)), the metal distal portion of the sleeve includes a converging surface and the distal portion of the dilator has an internal surface that is complementary

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to the converging surface of the metal distal portion (see Fig. 5(c)), and the distal portion of the catheter 5 or dilator 5 and the metal distal portion of the sleeve is curved.

9. Referring to **claims 58-60**, Fonger discloses tube 11 and 15 are made from stainless steel hypotubes (see col. 5, lines 5-25).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger (U.S. 5,190,528) in view of Gonzales et al (U.S. 6,855,124).**

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13. Fonger discloses the invention substantially as claimed except or the needle 9 is formed from thin walled tubing and the hardness of material of the tubing is less than the material of the sleeve. However, Gonzalez discloses (see Fig. 2) the a therapeutic needle for delivering a therapeutic agent to a vessel wall or within a cardiac chamber (see col. 2, lines 60-68) wherein the needle tip 210 is made from ceramic material which are compatible with MRI in that the materials do not introduce artifacts in MRI images (see col. 3, lines 54-64). It would have been obvious to one of ordinary skill in the art to made the needle of Fonger as suggested by Gonzalez so that it too would have the same advantage.
14. **Claims 11, 50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (US 5,190,528).**
15. Figures 5(b) and 5(c) disclose the catheter 5 or dilator has an inner tapered surface wherein the inner tapered surface complement with the rounded outer surface on the distal portion of sleeve 15, however, Fonger fails to disclose the sleeve 15 or transport tube has a bevel on an outer surface. It is old and well known in the art that conical chamfer or bevel designs are for ease of insertion and alignment during insertion of one component into another component. It would have been obvious to one of ordinary skill in the art to replace the rounded outer surface on the distal portion of sleeve 15 with a bevel so that it too would have the same advantage.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen  
November 01, 2007



Todd E. Manahan  
SPE 3731